510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

SCALPFIX CLIP SYSTEM

July 13, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

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800-258-1946 (phone)
610-231-3713 (fax)
lisa.millington@aesculap.com (email)

TRADE NAME: Scalpfix Clip System

COMMON NAME: Scalp Clip and Applier

DEVICE CLASS: SCALP CLIP – CLASS II
SCALP CLIP GUN – CLASS I – EXEMPT

PRODUCT CODE: Scalp Clip – 84 HBO
Scalp Clip Gun – 79 GDO

CLASSIFICATION: Scalp Clip – 882.4150
Scalp Clip Gun – 878.4800

REVIEW PANEL: Neurology

INTENDED USE

Aesculap's **Scalpfix** clip system is indicated for use in **temporary hemostasis of the scalp edge**.

DEVICE DESCRIPTION

Aesculap's scalp clip gun (FF012R) is a hand held manual instrument. It is used in conjunction with Aesculap's scalp clip (FF013P) to insert sterile plastic scalp clips at the margin of scalp wounds during operations on the cranium. The gun consists of a handle, trigger, magazine lock, and a magazine suspension pin.

The scalp clips are used for temporary hemostasis of the opened scalp. It has proven useful to use plastic clips to ligate the scalp during trepanation or large exposures of relatively long duration, thereby avoiding bleeding at the wound margin. Aesculap scalp clips are intended for single use only. They may not be resterilized. The scalp clips are packaged as 10 scalp clips per magazine in a box of 20 magazines.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new Scalpfix conforms to applicable ASTM and ISO standards.

SUBSTANTIAL EQUIVALENCE

The new ScalpFix Clip System described in this premarket notification is substantially equivalent to those in Aesculap's current Caspar Scalp Clip System (subjected to K890443) and the following other predicate devices:

- Acra-Cut (500-102 & 500-105) (K944311)
- Codman & Shurtleff Disposable Scalp Clip / Applier (K905433)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2001

Ms. Lisa M. Millington
Regulatory Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K012219
Trade/Device Name: Scalpfix Clip System
Regulation Number: 882.4150, 878.4800
Regulatory Class: II
Product Code: HBO, GDO
Dated: July 12, 2001
Received: July 16, 2001

Dear Ms. Millington:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012219

Device Name: Scalpfix

Indication for Use:

Aesculap's **Scalpfix** is indicated for use in temporary **hemostasis of the scalp edge.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012219